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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,721	12/14/2001	Motonao Nakao	033808/027 2535	9615

7590 10/23/2002
Pillsbury Winthrop LLP
Suite 200
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/23/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,721

Applicant(s)

NAKAO ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-4) in Paper No. 5 is acknowledged.
2. The Information Disclosure Statement (Paper No. 3) filed on July 30, 2002 has been entered and considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite 'detecting spots' which is unclear and confusing because it is not clear what these spots refer to, (that is do they represent detection of PCR-amplified base sequences or hybridization event). Amendment to properly reciting the invention would obviate this rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

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the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1- 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley (WO 98/22620) in view of Burgart et al.

With reference to the instant claim 1, Stanley teaches a method of detecting PCR-amplified base sequences, wherein Cronin et al. disclose that the method comprises conducting PCR amplification by mixing one or more PCR primers with the sample to amplifying a target nucleic acid of a sample (see page 4, lines 3-11, lines 16-22); conducting a hybridization reaction using a substrate-bound oligonucleotides (complementary to the target sequences) and detecting the hybridized PCR products on the substrate(see page 5, lines 11-19). With reference to the instant claim 3, Stanley teaches that the method comprises oligonucleotide primers having a base number ranging from 23-24 (seepage 14, lines 31-33).

Stanley also discloses that the method utilizes oligonulceotide primers to amplify a target nucleic acid and also used as probes to detect PCR amplified products in hybridization assay (see page 7, lines 1-4, page 16, lines 25-36, page 17, lines 1-18, and page 22, lines 4-9). However, Stanley did not teach plurality of primer pairs (multiplex PCR).

Burgart et al. teach a multiplex PCR wherein Bugart et al. disclose that the method comprises plurality of primer sets to amplify target regions in a sample (see page 320, abstract, column 3, paragraphs 1-2, page 321, column 1 and column 2). With reference to the instant claims 2 and 4, Burgart et al. also discloses that the method comprises detection of PCR-

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amplified products by fluorescent intercalating material, which intercalates double-stranded DNA (see page 321, column 2, lines 36-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting PCR-amplified base sequences by utilizing PCR primers for amplification and for detection of PCR amplified products in hybridization as probes, as taught by Stanley with the multiplex PCR detection of PCR-amplified products as taught by Burgart et al., which is applicable to detect plurality of target regions in a sample because Burgart states that 'multiplex PCR allows amplification of more than one fragments of DNA and reduces number of reaction tubes, conserves expensive reagents, decreases time required for experimentation and minimizes possible contamination' (see page 320, abstract, and paragraph 2). An ordinary practitioner would have been motivated to combine the method of detecting PCR-amplified products via hybridization as taught by Stanley with the use of plurality of PCR primers as taught by Burgart et al. for the advantages of reducing and conserving expensive reagents for PCR amplification by limiting the PCR amplification to plurality of primer pairs for expected benefit of analyzing multiple target sequences simultaneously on a solid support.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{SC}
Suryaprabha Chunduru
October 18, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER